INTERAGENCY AGREEMENT BETWEEN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE DEPARTMENT OF DEFENSE FOR SUPPORT OF CONTINGENCY MEDICAL MATERIEL REQUIREMENTS

References:

- (a) Section 121 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188, Title 42 United States Code 300hh-12
- (b) 10 U.S.C. Sections 113, 3013, 5013 and 8013
- (c) Public Health Service Act, as amended, 42 U.S.C. Sections 241 et seq.
- (d) The Robert T. Stafford Disaster Relief and Emergency Assistance Act, as amended, 42 U.S.C. Sections 5121 et seq.
- (e) National Response Plan, December, 2004
- (f) Homeland Security Presidential Directive (HSPD) 5, February 28, 2003
- (g) Presidential Decision Directive (PDD-39), June 21, 1995
- (h) DoD Instruction 2000.18, "Department of Defense Installation Chemical, Biological, Radiological, Nuclear and High-Yield Explosive Emergency Response Guidelines," December 4, 2002
- (i) DoD Directive 3015.1, "Military Support to Civil Authorities (MSCA)," January 15, 1993
- (j) DoD Directive 3025.15, "Military Assistance to Civil Authorities," February 18, 1997

1. Purpose

This Interagency Agreement (IA) between the Department of Health and Human Services (HHS) and the Department of Defense (DoD) establishes a framework to coordinate mutual support in the event of a shortfall in critical medical materiel (pharmaceuticals, biologics, medical / surgical supplies and equipment needed by HHS or DoD to prepare for, respond to or recover from the public health and medical consequences of a domestic catastrophic incident / incident of national significance.

2. Definitions

Terms used in this IA are defined in Attachment 1.

3. Substance of Agreement

3.1 This IA establishes procedures by which HHS can request delivery and transfer of DoD contingency materiel assets (defined in attachment 1). It also describes procedures by which DoD can request delivery and transfer of Strategic National

Stockpile (SNS) Program assets from HHS in a domestic emergency if needs are not met by the preferred mechanism as described in 4.1.1.

- 3.2 This IA underscores the importance of CONUS DoD Installation Commanders to participate in State, local, and regional planning for mutual support in preparation and response to a domestic incident of national significance.
- 3.3 In accordance with HSPD 5, the Secretary of Defense shall provide military support to civil authorities for domestic incidents as directed by the President or when consistent with military readiness and appropriate under the circumstances and the law.
- 3.4 DoD and HHS must work closely to develop mutual support arrangements that are in the best interest of overall federal response to a wide range of emergency medical situations. This IA will establish working relationships to address the intent of the National Incident Management System (NIMS) and the National Response Plan (NRP). To facilitate this working relationship, specific interdepartmental arrangements may be established related to the following and other aspects of medical materiel management:
 - 3.4.1. Collaboration on medical materiel planning and requirements.
- 3.4.2 Development and shared usage of modeling techniques and tools to determine requirements.
 - 3.4.3 Consolidated and/or joint procurement actions.
- 3.4.4 Collaboration on training and instructional materials related to receipt, management and distribution of the SNS and DoD contingency material stockpiles and use of the products within those stockpiles.
 - 3.4.5 Development of space allotments for DoD personnel to attend SNS training.
- 3.4.6 Sharing of information that broadly details the scope of materiel that each department may be able to provide.
- 3.4.7 Sponsorship of and participation in interdepartmental coordinating groups related to medical materiel management.
- 3.4.8 Development of a process that facilitates one agency's access to the use of an investigational drug or medical device for which the other agency is the holder of the IND or IDE. Similar arrangements should be made for products for use under Emergency Use Authorization.

4. Request Process

- 4.1 Requests <u>initiated by DoD</u>: DoD requests for delivery and transfer of SNS assets shall be initiated through military command channels leading to the Office of the Secretary of Defense who will serve as the DoD requesting agency to HHS.
- 4.1.1 Reference (h) instructs military installations to coordinate and integrate chemical, biological, radiological, nuclear and high-yield explosive (CBRNE) installation response plans with state and local emergency response plans as necessary. This coordination and integration will result in military installations normally receiving SNS assets as part of the State and local governments' SNS distribution plan. However, the unique challenges of responding to a CBRNE event may result in a situation requiring DoD to request SNS assets directly from HHS. These requests will be separate from the established State and local governments' SNS request protocol. In this situation, SNS assets provided to DoD will be in specific configurations on a case-by-case basis. Military installations are likely to receive SNS managed inventory rather than a 12-hour Push Package. Insofar as SNS assets are generally designated for resupply and sustainment of a response, DoD Installation Commanders will not rely on the SNS as part of their initial response capability.
- 4.2 Requests <u>initiated by HHS</u>: Response to a domestic incident of national significance affecting the domestic civil sector may produce a situation in which HHS may need to request delivery and transfer of DoD contingency medical materiel to supplement its response to an emergency situation. Given such a situation, HHS will serve as the requesting official to DoD and initiate the Request for Assistance (RFA) regarding the delivery and transfer of DoD contingency medical materiel.
- 4.2.1 The entry point for RFAs into the Office of the Secretary of Defense (OSD) is the OSD Executive Secretariat. Under emergency situations, verbal RFAs will be accepted, but must be followed by a formal written request for DoD assistance.

5. Funding

5.1 Under the provisions of the Stafford Act, Title 42, United States Code, Section 5121, et seq, as amended, if the President declares an emergency or disaster, he may direct any Federal agency, with or without reimbursement, to use authorities and resources granted to it under the Federal law in support of State and local assistance efforts. Presidential Decision Directive (PDD)-39 states federal agencies directed to participate in the resolution of terrorist incidents or conduct of counterterrorist operations bear the costs of their own participation unless otherwise directed by the President. In support of Non-Stafford Act incidents of national significance, Economy Act, Title 31, United States Code, Section 1535, or other applicable authorities apply.

6. Responsibilities

- 6.1 Assistant Secretary of Defense for Homeland Defense (ASD (HD)) shall:
- 6.1.1 As the Principal Staff Assistant and advisor to the Under Secretary of Defense for Policy, and the Secretary and Deputy Secretary of Defense for all DoD HD activities, promptly coordinate the Lead Federal Agency RFA for appropriate action.
- 6.1.2 In consultation with Assistant Secretary of Defense for Health Affairs (ASD (HA)), prepare and forward DoD priorities for SNS Program assets to the Secretary of Defense or Deputy Secretary of Defense for action. Upon approval, coordinate the submission of DoD's official request to HHS.
 - 6.1.3 Coordinate and exchange information and issues pertaining to DOD's priorities for SNS Program assets with other OSD PSAs and other Federal officials having collateral or related functions.
 - 6.1.4 Designate and provide liaison officers as required.
 - 6.2 Assistant Secretary of Defense for Health Affairs (ASD (HA)) shall:
- 6.2.1 As the principal staff assistant and advisor to the Under Secretary of Defense for Personnel & Readiness, and the Secretary and Deputy Secretary of Defense for all DoD health policies, programs and activities, provide technical expertise and advice to identify, establish and recommend DoD priorities regarding the allocation of SNS Program assets from the HHS.
 - 6.2.2 Designate and provide liaison officers as required.
- 6.3 Under Secretary of Defense for Acquisition, Technology and Logistics (USD (AT&L)) shall:
- 6.3.1 Notify key DoD logistics agencies, and as required locate and coordinate the release of required DoD contingency medical materiel.
- 6.3.2 In coordination with ASD (HD), and ASD (HA), obtain through the Chairman of the Joint Chiefs of Staff, information regarding the status of critical medical materiel needed to support the Combatant Command (s) and Service priorities.
- 6.3.3 When appropriate, obtain through the Chairman of the Joint Chiefs of Staff, information regarding the availability of Service owned medical material that could be provided to HHS.

- 6.3.4 As required, coordinate the delivery and transfer of DoD contingency medical materiel with appropriate HHS agencies. Coordination/dialogue continue until materiel is delivered and transferred.
 - 6.3.5 Designate and provide liaison officers as required.
- 6.4 Department of Health and Human Services (HHS), Office for Public Health Emergency Preparedness (OPHEP) shall:
- 6.4.1 Provide technical expertise and advice to identify, establish and recommend HHS priorities regarding the allocation of DoD contingency medical materiel.
- 6.4.2 Serve as the requesting official to DoD, and initiate and forward RFA regarding the delivery and transfer of DoD contingency medical materiel.
 - 6.4.3 Serve as the sole portal for requests from DoD under this agreement.
- 6.4.4 Coordinates delivery and transfer of SNS Program assets with appropriate DoD stakeholders. Coordination/dialogue continue until materiel is delivered and transferred.
 - 6.4.5 Designate and provide liaison officers as required.

7. Period of Agreement

This Agreement, when approved by all parties, will continue indefinitely. This Agreement may be modified or revised by subsequent agreement of all parties. This Agreement may be terminated by any party upon 30 days written notice.

Approved for the Department of Defense

Paul McHale

Assistant Secretary of Defense

(Homeland Defense)

0 5 MAY 2005

Attachment: As stated

Approved for the

Department of Health & Human

Services -

Bv:

Stewart Simonson

Assistant Secretary

(Public Health Emergency Preparedness)

ATTACHMENT 1 - DEFINITIONS

- 1. <u>Catastrophic Incident</u>. Any natural or manmade incident, including terrorism, that results in extraordinary levels of mass casualties, damage, or disruption severely affecting the population, infrastructure, environment, economy, national morale, and/or government functions. A catastrophic event could result in sustained national impacts over a prolonged period of time; almost immediately exceeds resources normally available to State, local, tribal, and private-sector authorities in the impacted area; and significantly interrupts governmental operations and emergency services to such an extent that national security could be threatened. All catastrophic events are Incidents of National Significance¹.
- 2. <u>Chemical, Biological, Radiological, Nuclear, and High-Yield Explosive</u> (<u>CBRNE</u>) <u>Incident</u>. The deliberate or inadvertent release CBRNE devices with potential to cause significant numbers of casualties and high levels of destruction².
- 3. <u>Contingency</u>. An emergency involving military forces caused by natural disaster, terrorists, subversives, or required by military operation. Due to the uncertainty of the situation, contingencies require plans, rapid response, and special procedures to ensure the safety and readiness of personnel, installations, and equipment.
- 4. Contingency Medical Materiel. Pharmaceuticals- antivirals, vaccines, medical surgical supplies and equipment which may be used or required by State and local jurisdictions, the Department of Health and Human Services (HHS), and the Department of Defense (DoD) to prepare for and or respond to medical emergencies resulting from natural or technological disasters, threats or actual acts of terrorism, and military operations. The DoD's contingency medical materiel includes both operational and war reserve stocks held in military or commercial storage locations. HHS maintains the Strategic National Stockpile (SNS). SNS materiel includes 12-hour Push Packages and stockpile-managed inventory.
- 5. <u>Domestic</u>. The commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the former territories of the Pacific Islands, the commonwealth of the Northern Mariana Islands, the Republic of the Marshall Islands, the District of Columbia, or any political subdivision thereof.
- 6. <u>High Yield Explosive</u>. Any weapon/device that is capable of a high order of destruction and/or of being used to kill or injure large numbers of people³.

¹ National Response Plan, "Appendix 1, Glossary of Key Terms," December, 2004

² <u>DoD Instruction 2000.18</u>, "DoD Installation Chemical, Biological, Radiological, Nuclear, and High Yield Explosive Emergency Response Guidelines," December 4, 2002

³ National Response Plan, "Appendix 1, Glossary of Key Terms," December, 2004

- 7. Incident of National Significance. Based on criteria established in HSPD-5 (paragraph 4), an actual or potential high-impact event that requires a coordinated and effective response by and appropriate combination of Federal, State, local, tribal, non-governmental, and/or private sector entities in order to save lives and minimize damage, and provide the basis for long-term community recovery and mitigation activities⁴.
- 8. <u>Public Health Emergency</u>. An occurrence or imminent threat of an illness or health condition caused by biological warfare or terrorism, epidemic or pandemic disease, or highly fatal infectious agent or biological toxin, which poses a substantial risk of a significant number of human fatalities or severe disabilities.
- 9. <u>Strategic National Stockpile</u>. A national repository of antibiotics, chemical antidotes, antitoxins, life support medications, intravenous administration, airway maintenance supplies, and medical/surgical items. The SNS supplements overwhelmed or depleted state and local medical material needed for the medical consequences of CBRNE events, natural disasters, industrial accidents, public health or other emergencies.

⁴ <u>DoD Instruction 2000.18</u>, "DoD Installation Chemical, Biological, Radiological, Nuclear, and High Yield Explosive Emergency Response Guidelines," December 4, 2002